



Express Mail No.: EV452776405US

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:

Kroczek

Confirmation No.:

9651

Serial No.:

10/647,072

Art Unit:

1644

Filed:

August 22, 2003

Examiner:

To Be Assigned

For:

COSTIMULATING POLYPEPTIDE OF T

Attorney Docket No.:

709181-999261

CELLS, MONOCLONAL ANTIBODIES,

AND THE PREPARATION AND USE **THEREOF** 

Attorney Ref. No.

7853-267-999

# REQUEST FOR CORRECTION OF FILING RECEIPT

**Commissioner for Patents** P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Applicant encloses herewith the Updated Filing Receipt and a copy thereof indicating in red the necessary corrections in connection with the above-identified application. Specifically, the filing receipt reflects an error in the title of the Application. The title "CONSTIMULATING POLYPEPTIDE OF T CELLS, MONOCLONAL ANTIBODIES, AND THE PREPARATION AND USE THEREOF" is incorrect; the title should recite instead "COSTIMULATING POLYPEPTIDE OF T CELLS, MONOCLONAL ANTIBODIES, AND THE PREPARATION AND USE THEREOF". As evidence of the correct title, enclosed is a copy of the page 1 of the present application, on which the title is highlighted. Applicant respectfully requests that the title be corrected in the file of the above-identified application.

No fee is believed due. However, should the Patent Office determine otherwise, the Commissioner is hereby authorized to charge any required fee(s) to Jones Day Deposit Account No. 50-3013. A copy of this sheet is enclosed for such purpose.

Respectfully submitted,

Date:

June 8, 2006

Nikolaos C. George JONES DAY

222 East 41st Street

New York, New York 10017

(212) 326-3939

by: mune alm Shoen

NYJD-1618281v1



UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address COMMISSIONER FOR PATENTS FO. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

**FILING OR 371** APPL NO. FIL FEE REC'D ART UNIT ATTY.DOCKET NO TOT CLMS **DRAWINGS** IND CLMS (c) DATE 10/647.072 08/22/2003 1644 1994 709181-999261 16 76 4

20583 JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017

MAR 2 7 2006 M. abu-Shaar **CONFIRMATION NO. 9651** 

UPDATED FILING RECEIPT

\*OC00000018361066\*

007853-0267-999

Date Mailed: 03/23/2006

Receipt is acknowledged of this regular Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please mail to the Commissioner for Patents P.O. Box 1450 Alexandria Va 22313-1450. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

Applicant(s)

Richard Kroczek, Berlin, GERMANY;

Power of Attorney: None

Domestic Priority data as claimed by applicant

This application is a CON of 09/509,283 08/11/2000 which is a 371 of PCT/DE98/02896 09/23/1998

Foreign Applications

GERMANY 19741929.1 09/23/1997 GERMANY 19821060.4 05/11/1998

If Required, Foreign Filing License Granted: 12/30/2003

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is US10/647,072

Projected Publication Date: Not Applicable

Non-Publication Request: No

**Early Publication Request: No** 

**Title** 

Constimulating polypeptide of T cells, monoclonal antibodies, and the preparation and use thereof

## **Preliminary Class**

536

## PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4158).

LICENSE FOR FOREIGN FILING UNDER
Title 35, United States Code, Section 184
Title 37, Code of Federal Regulations, 5.11 & 5.15

#### GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

#### **NOT GRANTED**

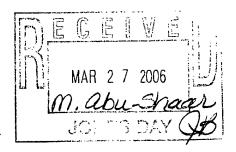
No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).



UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. SON 1459 Alexandra, Virginia 22313-1450 www.unpto.gov

**FILING OR 371** APPL NO. ART UNIT FIL FEE REC'D ATTY.DOCKET NO **TOT CLMS** DRAWINGS IND CLMS (c) DATE 10/647.072 08/22/2003 J 1644 V 1994 709181-999261 16 76 4

20583 JONES DAY **222 EAST 41ST ST** NEW YORK, NY 10017



**CONFIRMATION NO. 9651** 

**UPDATED FILING RECEIPT** 

\*OC000000018361066\*

007853-0267-999

Date Mailed: 03/23/2006

Receipt is acknowledged of this regular Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please mail to the Commissioner for Patents P.O. Box 1450 Alexandria Va 22313-1450. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

Applicant(s)

Richard Kroczek, Berlin, GERMANY:

Power of Attorney: None

Domestic Priority data as claimed by applicant

This application is a CON of 09/509.283 08/11/2000 which is a 371 of PCT/DE98/02896 09/23/1998

Foreign Applications

GERMANY 19741929.1 09/23/1997 GERMANY 19821060.4 05/11/1998

If Required, Foreign Filing License Granted: 12/30/2003

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US10/647,072** 

Projected Publication Date: Not Applicable

Non-Publication Request: No

Early Publication Request: No

**Title** 

Costimulating

Constimulating polypeptide of T cells, monoclonal antibodies, and the preparation and use thereof

**Preliminary Class** 

536

### PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4158).

# LICENSE FOR FOREIGN FILING UNDER Title 35, United States Code, Section 184 Title 37, Code of Federal Regulations, 5.11 & 5.15

#### **GRANTED**

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

#### **NOT GRANTED**

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

# Costimulating Polypeptide of T Cells, Monoclonal Antibodies,

## And the Preparation and Use Thereof

This application claims priority of U.S. patent application Serial No. 09/509,283, filed August 11, 2000, which claims priority to PCT Application PCT/DE98/02896, filed September 23, 1998, and German Applications DE 19821060.4, filed May 11, 1998, and DE 19741929.1, filed September 23, 1997, each of which is incorporated herein by reference in its entirety.

[001] The invention relates to a polypeptide (8F4 molecule) having the biological activity of costimulating T cells. The invention further relates to monoclonal antibodies against the 8F4 molecule and hybridoma cells which produce the monoclonal antibodies. The invention additionally relates to the use of substances which inhibit the biological activity of the polypeptide 8F4 according to the invention, in particular monoclonal antibodies, natural or synthetic ligands, agonists or antagonists, as pharmaceuticals. In particular, the invention relates to the use of these substances for the prevention or therapy of disorders in which the immune system is involved, in particular for the treatment of autoimmune diseases and for the prevention of rejection reactions with organ transplants. The invention additionally relates to the use of the 8F4 molecule or of cells which contain the 8F4 molecule as pharmaceuticals, in particular for the prevention or therapy of disorders in which the immune system is involved, in particular for the treatment of cancers, Aids, asthmatic disorders or chronic viral diseases such as HCV or HBV infections. The invention further relates to the use of substances which specifically recognize the polypeptide according to the invention, in particular monoclonal antibodies, natural or synthetic ligands, agonists or antagonists, for the diagnosis of disorders in which the immune system is involved. In particular, the invention relates to diagnosis by means of an ELISA detection, a flow cytometry or a Western blot, a radioimmunological detection, a nephelometry or a histochemical staining.

[002] T lymphocytes recognize their antigen, which is presented by "antigen-presenting cells", for example dendritic cells, B cells and macrophages, through their T-cell receptor.

Recognition of the antigen by the T-Cell receptor alone is, however, in most cases insufficient